SWABEY OGILVY MTL 514 288 8389

Patent

Docket No. 2139-11US - CC:lcl

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Yasuo KONISHI et al.

Serial No.: 09/529,232

Group Art Unit: 1655

Filed:

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Examiner: Janelle TAYLOR

For:

TRIVALENT THROMBIN INHIBITOR

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents and Trademarks
Washington, DC 20231

Sir:

In response to the Office Action of December 19, 2001, please consider the following remarks. This response is being filed concurrently with a petition for a 2-month extension of time.

In response to the Outstanding Restriction Requirement, Applicants elect with traverse group XXIV, drawn to sequence 24 of claim 5.

The Restriction Requirement is respectfully traversed with respect to groups I to XXIII, as the Applicant respectfully submit that there is a unity of invention between those groups, i.e., the specific compound of Formula 1 as defined in claim 1. It is to be noted that claim 5 is being dependent on claim 1, and only further define claim 1 with respect to specific sequences.

Furthermore, it is respectfully submitted that groups I to XXIV, all defining specific subset sequences of formula 1 as defined in claim 1, would all pertain to the same

Assistant Commissioner for Patents

class and subclass and therefore, would not impose a serious burden on the Examiner to examine all these inventions.

Under the statute, an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP Subsection 806.04 to Subsection 806.04(j) or distinct (MPEP Subsection 806.05 to Subsection 806.05(i)).

According to the MPEP, there are two criteria for proper requirements for restriction between patentably distinct inventions:

- 1) The inventions must be independent (see MPEP Subsection 802.01, Subsection 806.04, Subsection 808.01) or distinct as claimed (see MPEP Section 806.05 to Subsection 806.05 (i)); and
- There must be a serious burden on the Examiner if restriction is not required (see MPEP Subsection 803.02, Subsection 806.04(a)-(j), Subsection 808.01(a) and Subsection 808.02).

It is believed that the inventions, as defined in the various sequences claimed in claim 5, are not independent and would not cause a serious burden on the Examiner. The Examiner alleges that the inventions listed as groups I to XXIV do not relate to a single general inventive concept under PCT Rule 13.01. In this respect, the Applicant respectfully disagrees, as unity of invention was not even questioned during the international phase of the present application. Therefore, it was believed that the claims as now on file had unity of invention in accordance with Rule 13.01 PCT. Since the International Bureau was of the opinion that there is unity of invention, and thus that there is a single general inventive concept under PCT Rule 13.01, it is respectfully submitted that restriction should not be required in view of *in re* Lee (199 USPQ 108 (Deputy Asst.

Assistant Commissioner for Patents

Comm'r. for Pats 1978). Therefore, the requirements of MPEP Subsection 803 are not met.

Furthermore, no prima facie case of a serious burden on the Examiner has been shown by appropriate explanation of separate classification or separate status in the art or different field of search, as defined in MPEP Subsection 808.02. Therefore, it is believed that no serious burden is imposed on the Examiner for searching these inventions.

Furthermore, as the Examiner will note, the various groups of inventions are all claimed in a Markush-type claim. MPEP Subsection 803.02 specifies that:

"Broadly, unity of invention exists where compounds included within the Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility."

In this respect, the Examiner will find throughout the application and also in the preamble of the claims, the common utility to each of these sequences, and will also find a substantial structural feature disclosed in claim 1. In fact, the only variation within all the sequences defined in claim 5 is the XAA and YAA amino acids in group Z within formula 1. Therefore, and even more, it is believed that restriction requirement is improper.

In view of the above, withdrawal of the restriction requirement and examination of claims 1 to 14 on the merits are therefore respectfully requested.

In the event that there are any questions concerning this Response, or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of the application may be expedited.